

(51) International Patent Classification 5 : A61F 13/02		A1	(11) International Publication Number: . WO 93/00056
			(43) International Publication Date: 7 January 1993 (07.01.93)
(21) International Application Number: PCT/DK92/00197 (22) International Filing Date: 23 June 1992 (23.06.92) (30) Priority data: 1227/91 24 June 1991 (24.06.91) DK (71) Applicant (for all designated States except US): COLO-PLAST A/S [DK/DK]; Egevangen 4, DK-2980 Kokkedal (DK). (72) Inventor; and (75) Inventor/Applicant (for US only) : SAMUELSEN, Peter, Boman [DK/DK]; Bukkeballevvej 18, DK-2960 Rungsted Kyst (DK). (74) Agent: HOFMAN-BANG & BOUTARD A/S; Adelgade 15, DK-1304 Copenhagen K (DK).		(81) Designated States: JP, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IT, LU, MC, NL, SE). Published <i>With international search report.</i>	
(54) Title: A BANDAGE OR DRESSING FOR COVERING WOUNDS			
(57) Abstract A skin-friendly dressing, comprising a moisture absorbing, to skin and mucous membranes adhering adhesive sheet, consisting of a layer of a water swellable colloid (10) which is dispersed in or mixed with a water insoluble viscous elastomer binder (9) and, if desired, usual auxiliary materials, the adhesive sheet at one outwardly directed surface being firmly connected to a non-adhesive water impervious cover layer (6), and at the other against the skin or mucous membrane directed surface of the adhesive sheet being provided with a removable protecting sheet (7). The adhesive sheet is provided with one or several grooves or ditches (2, 3) that fully or partly surround a central part (4) of the adhesive sheet. The dressing has a high moisture absorbing capacity, a high degree of flexibility and a good integrity.			

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	FI	Finland	ML	Mali
AU	Australia	FR	France	MN	Mongolia
BB	Barbados	GA	Gabon	MR	Mauritania
BE	Belgium	GB	United Kingdom	MW	Malawi
BF	Burkina Faso	GN	Guinea	NL	Netherlands
BG	Bulgaria	GR	Greece	NO	Norway
BJ	Benin	HU	Hungary	PL	Poland
BR	Brazil	IE	Ireland	RO	Romania
CA	Canada	IT	Italy	RU	Russian Federation
CF	Central African Republic	JP	Japan	SD	Sudan
CG	Congo	KP	Democratic People's Republic of Korea	SE	Sweden
CH	Switzerland			SN	Senegal
CI	Côte d'Ivoire	KR	Republic of Korea	SU	Soviet Union
CM	Cameroon	LI	Liechtenstein	TD	Chad
CS	Czechoslovakia	LK	Sri Lanka	TG	Togo
DE	Germany	LU	Luxembourg	US	United States of America
DK	Denmark	MC	Monaco		
ES	Spain	MG	Madagascar		

- 1 -

A bandage or dressing for covering wounds

5 The present invention refers to a skin-friendly bandage or dressing for covering wounds, burns or similar damages of the human skin, or ostomi openings.

10 From US Patent No. 4 867 748 is known a skin-friendly dressing comprising a water soluble or water swellable hydrocolloid, a water-insoluble, viscous elastomeric binder and optionally also a tackifying resin. This known dressing is formed as a sealing pad having bevelled outer edges and optionally also, if annular, a bevelled inner edge.

15 The dressings described in this and other similar patents are rather stiff as they must have a considerable thickness in order to contain a sufficient amount of moisture absorbing materials.

20 An object of the present invention is to provide a bandage or wound dressing having a high moisture absorbing capacity and simultaneously a high degree of flexibility for covering surface areas of the human body.

25 It is also an object of the invention to provide a bandage or wound dressing comprising a medicament or a similar physiologically active material that may be transferred to the skin or mucous membranes to which the bandage or
30 dressing is adhered.

According to the invention it has been found that a surprisingly high degree of flexibility may be obtained without compromising the integrity and the absorbing
35 properties when the bandage or wound dressing is provided with grooves or ditches.

- 2 -

The skin-friendly bandage or dressing according to the invention comprises a moisture absorbing, to skin and mucous membranes adhering adhesive sheet, consisting of a layer
5 of a water swellable colloid which is dispersed in or mixed with a water insoluble viscous elastomer binder and, if desired, usual auxiliary materials, the adhesive sheet at one outwardly directed surface being firmly connected to a non-adhesive water impervious cover layer, and the
10 other against the skin or mucous membrane directed adhesive surface being provided with a removable protecting sheet. The bandage or wound dressing is specifically characterized in that the adhesive sheet is provided with one or several grooves or ditches that fully or partly
15 surround the central part of the adhesive sheet.

The swellable colloid particles preferably consist of one or more water soluble or water swellable hydrocolloid polymers or gums. Suitable examples are
20 carboxymethylcellulose, dextran, pectin, guar gum and polyvinylalcohol. Further examples of such materials are mentioned in US 4 867 748, EP 0 122 344.

The elastomer binder, acting as a medium for dispersing
25 the hydrocolloid particles, is any known water-insoluble elastomeric substance, preferably a polymer or copolymer. Suitable examples are polyisobutylene, silicone rubber, acrylonitrile rubber, polyurethane etc. Further examples may be derived from the above mentioned EP 0 122 344.

30 If desired, any common used auxiliary material may be included as a component of the dressing, such as antioxidants, for example butylated hydroxyanisole or hydroxytoluene, deodorants such as chlorophyllins, or
35 perfume agents. It is also common practice to add pharmacologically active ingredients in the adhesive

- 3 -

composition, such as antibiotic or antimicrobial agents, such as neomycin, an antiseptic agents such as povidone iodine, and/or an antiinflammatory agent such as hydrocortisone or triamcinolone acetomide.

5

Further examples of such auxiliary are enumerated in the literature, see for example EP 0 122 344, EP 0 340 945, US 3 972 328, and US 4 867 748.

- 10 The impervious cover layer may consist of any known useful material for the purpose. Examples of such materials are any film forming polymer, such as polyethylene, polypropylene, polyester, polyvinylchloride, polyvinyliden-chloride, polyvinylacetate, polyamide, polyvinylether and
15 polyurethane. The impervious cover layer may also be a foam, such as polyurethane foam or polyether foam.

- The bandage or wound dressing may, according to an embodiment of the invention, have a hole in the central
20 part.

- The grooves or ditches may preferably have such a depth that the thickness of the sheet at the bottom of the ditch is less than 1/4 of the thickness of the sheet between the
25 ditches. The width of the grooves or ditches is up to three times the depth and, preferably, the width has the same size as the depth. A maximum of flexibility is thus obtained.

- 30 The grooves or ditches impart highly increased flexibility to the dressing.

The invention shall be further described in connection with the drawing, where

35

Fig. 1, 4 and 5 are three different embodiments of the

- 4 -

bandage according to the invention, seen from above,

Fig. 2, 3 and 6 illustrate various forms of grooves or ditches in the bandage, and

5

Fig. 7 illustrates a special embodiment in which only a distal part of the bandage has grooves.

10 The bandage illustrated in fig. 1 consists of a circular sheet with an outer edge 1 and two grooves 2, 3. The central part 4 has a uniform maximum thickness. As shown in fig. 2, 3 and 6 the grooves may have different profiles such as V- or U-shapes. An impervious cover layer 6
15 placed on top of the outer surface. The surface to be placed against the skin is provided with adhesive layer 8 covered by a protective removable film 7.

20 One or two concentric grooves improves considerably the resistance to radial swelling. This property may be measured by a method described below.

The central part 4 may be a hole as illustrated in fig. 4.

25 This embodiment is suitable as bandage for ostomi openings. Increased flexibility is obtained due to concentric ditches 3 as well as radial ditches 2. Such a bandage can be rather thick having a high absorption capacity and still being highly flexible.

30

The bandage shown in fig. 5 has an elliptical outer edge 1. The bandage shown in fig. 7 is intended to be placed at a vertical surface of a body area, the distal part directed downward in order to minimize swelling in the
35 downward direction.

- 5 -

The dressings according to the invention may be manufactured in various ways, e.g. by a die-casting process or a pressing process. An adequate method of manufacturing the dressing is disclosed by US 4 867 748.

5

Method of determining radial swelling

10 An apparatus of a sheet of glass (25 x 25 cm) with a central hole of 20 mm is connected to a reservoir of water via a tube mounted on to the said hole. At the side opposite to the tube of the sheet of glass the product to be tested is applied with the hole as centrum. Physiological saline is introduced to the product adhering to the glass sheet by elevating the reservoir for said saline to a
15 position above the product. A pressure of 2-10 cm of water column is applied to the product and the radially swelling from the hole out through the product may be determined. The test is performed at 37 °C and readings are taken at the times; 6 hours, 24 hours, 2, 3 and 4 days. The glass
20 plate is placed horizontally in the test.

The invention is further illustrated by the following examples.

25 Example 1

A test product from the category of hydrocolloid dressings and with a content of 40% particles of sodiumcarboxymethyl-cellulose dispersed in an elastomeric binder consisting of polyisobutylene and covered by a polyurethane
30 film of 30 μ was tested as a plane sheet and formed with 2 grooves as shown in fig. 1. The grooves are concentric and centrally placed with deformation diameters of 24 mm and 34 mm.

35

The radial swellings at 12 hours are identical for the two

- 6 -

dressings. However, when passing the first deformation after 24 hours a decrease in radial swelling velocity of 13% is observed for the deformed version and this decrease has after further 3 days further increased to a level of 30%.

Example 2

A product configuration comprising the same materials as mentioned in example 1 and especially intended for leg ulcers was investigated. Here a considerable radial swelling component exists due to gravity. This means that the distal or downward part of a hydrocolloid dressing will swell more quickly than the rest of the product and hence give rise to product change although there may be considerable swelling capacity left in the product in total. By only deforming the distal part of the product by compartments as in the figure 7 and testing it by described method placing the glass sheet vertically the period before distal leakage is improved with 18-23% when the hydrocolloid dressing is deformed compared to the identified control without deformation.

25

30

35

- 7 -

P a t e n t C l a i m s :

1. A skin-friendly dressing, comprising a moisture absorbing, to skin and mucous membranes adhering adhesive sheet, consisting of a layer of a water swellable colloid (10) which is dispersed in or mixed with a water insoluble viscous elastomer binder (9) and, if desired, usual auxiliary materials, the adhesive sheet at one outwardly directed surface being firmly connected to a non-adhesive water impervious cover layer (6), and at the other against the skin or mucous membrane directed surface of the adhesive sheet being provided with a removable protecting sheet (7), c h a r a c t e r i z e d in that the adhesive sheet is provided with one or several grooves or ditches (2, 3) that fully or partly surround a central part (4) of the adhesive sheet.
2. A bandage or dressing according to claim 1, c h a r a c t e r i z e d in that the central part (4) is a hole.
3. A bandage or dressing according to claim 1, c h a r a c t e r i z e d in that at least one of the grooves or ditches is arranged concentric around the central part (4).
4. A bandage or dressing according to claim 1, c h a r a c t e r i z e d in that at least some of the grooves or ditches are arranged radially outwardly from the central part (4).
5. A bandage or dressing according to any of the preceding claims, c h a r a c t e r i z e d in that said grooves or ditches have such a depth that the thickness of the sheet at the bottom of the ditch is less than $\frac{1}{4}$ of the

- 8 -

thickness of the sheet between the ditches.

5

10

15

20

25

30

35

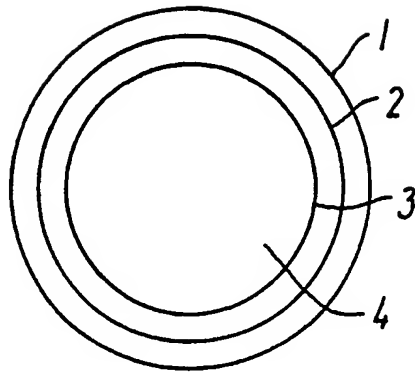


FIG. 1

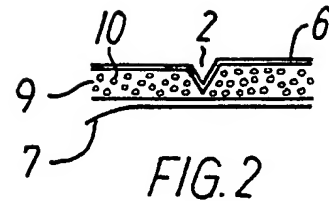


FIG. 2

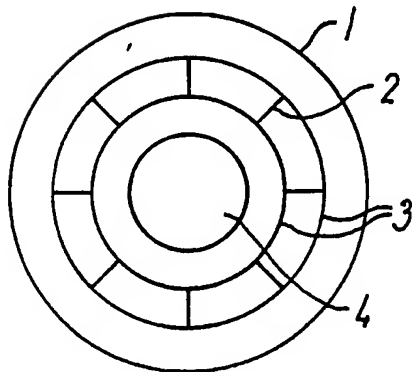


FIG. 4

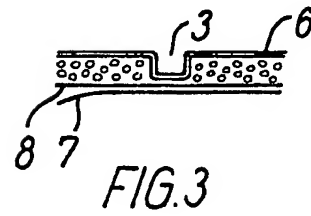


FIG. 3

2/2

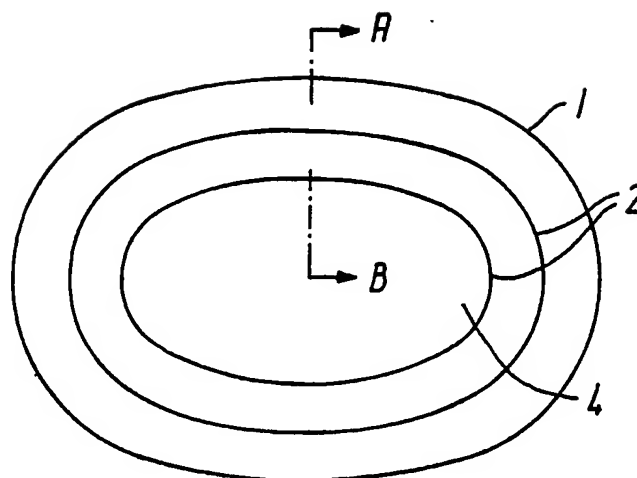


FIG. 5



FIG. 6

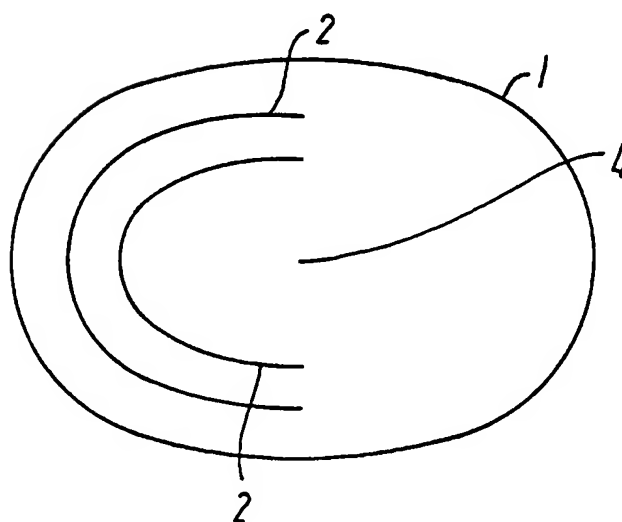


FIG. 7

INTERNATIONAL SEARCH REPORT

International Application No PCT/DK 92/00197

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) ⁶ According to International Patent Classification (IPC) or to both National Classification and IPC IPC5: A 61 F 13/02														
II. FIELDS SEARCHED <div style="text-align: center; border-top: 1px solid black; border-bottom: 1px solid black;">Minimum Documentation Searched⁷</div> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 25%; border-bottom: 1px solid black;">Classification System</td> <td style="border-bottom: 1px solid black;">Classification Symbols</td> </tr> <tr> <td style="height: 40px; vertical-align: bottom;">IPC5</td> <td style="vertical-align: bottom;">A 61 F</td> </tr> </table> <div style="text-align: center; border-top: 1px solid black; border-bottom: 1px solid black;">Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in Fields Searched⁸</div> <p>SE,DK,FI,NO classes as above</p>			Classification System	Classification Symbols	IPC5	A 61 F								
Classification System	Classification Symbols													
IPC5	A 61 F													
III. DOCUMENTS CONSIDERED TO BE RELEVANT⁹ <table style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 10%; border-bottom: 1px solid black;">Category *</th> <th style="width: 60%; border-bottom: 1px solid black;">Citation of Document,¹¹ with indication, where appropriate, of the relevant passages¹²</th> <th style="width: 30%; border-bottom: 1px solid black;">Relevant to Claim No.¹³</th> </tr> <tr> <td style="vertical-align: top; text-align: center;">X</td> <td>EP, A2, 0164319 (COLOPLAST A/S) 11 December 1985, see abstract; page 3, line 31 - page 4, line 5 --</td> <td style="vertical-align: top; text-align: center;">1-5</td> </tr> <tr> <td style="vertical-align: top; text-align: center;">A</td> <td>EP, A2, 0230373 (ETHICON INC.) 29 July 1987, see the whole document --</td> <td style="vertical-align: top; text-align: center;">1-5</td> </tr> <tr> <td style="vertical-align: top; text-align: center;">A</td> <td>EP, A2, 0264299 (COLOPLAST A/S) 20 April 1988, see the whole document -- -----</td> <td style="vertical-align: top; text-align: center;">1-5</td> </tr> </table>			Category *	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³	X	EP, A2, 0164319 (COLOPLAST A/S) 11 December 1985, see abstract; page 3, line 31 - page 4, line 5 --	1-5	A	EP, A2, 0230373 (ETHICON INC.) 29 July 1987, see the whole document --	1-5	A	EP, A2, 0264299 (COLOPLAST A/S) 20 April 1988, see the whole document -- -----	1-5
Category *	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³												
X	EP, A2, 0164319 (COLOPLAST A/S) 11 December 1985, see abstract; page 3, line 31 - page 4, line 5 --	1-5												
A	EP, A2, 0230373 (ETHICON INC.) 29 July 1987, see the whole document --	1-5												
A	EP, A2, 0264299 (COLOPLAST A/S) 20 April 1988, see the whole document -- -----	1-5												
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>* Special categories of cited documents:¹⁰</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 50%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance, the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance, the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p> </div> </div>														
IV. CERTIFICATION <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; border-bottom: 1px solid black;">Date of the Actual Completion of the International Search</td> <td style="width: 50%; border-bottom: 1px solid black;">Date of Mailing of this International Search Report</td> </tr> <tr> <td style="height: 40px; vertical-align: bottom;">30th September 1992</td> <td style="vertical-align: bottom; text-align: center;">05 -10- 1992</td> </tr> <tr> <td style="border-bottom: 1px solid black;">International Searching Authority</td> <td style="border-bottom: 1px solid black;">Signature of Authorized Officer</td> </tr> <tr> <td style="height: 40px; vertical-align: bottom; text-align: center;">SWEDISH PATENT OFFICE</td> <td style="vertical-align: bottom; text-align: center;"> Jack Hedlund </td> </tr> </table>			Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	30th September 1992	05 -10- 1992	International Searching Authority	Signature of Authorized Officer	SWEDISH PATENT OFFICE	 Jack Hedlund				
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report													
30th September 1992	05 -10- 1992													
International Searching Authority	Signature of Authorized Officer													
SWEDISH PATENT OFFICE	 Jack Hedlund													

**ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO. PCT/DK 92/00197**

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the Swedish Patent Office EDP file on 28/08/92. The Swedish Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP-A2- 0164319	85-12-11	US-A- 4699134	87-10-13
EP-A2- 0230373	87-07-29	CA-A- 1265400	90-02-06
		JP-A- 62243557	87-10-24
		US-A- 4612230	86-09-16
EP-A2- 0264299	88-04-20	US-A- 4867748	89-09-19

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☐ FADED TEXT OR DRAWING
- ☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☒ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.